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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,283	04/09/2004	Britta Hardy	85189-6100	9624

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,283	HARDY ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 25, and 33, drawn to peptide comprising SEQ ID NO: 1, 2, or 6-10, classified in class 530, subclass 300.

II. Claims 1, 3-5, 7, 9, 25, and 33, drawn to peptide comprising SEQ ID NO: 3-5, classified in class 530, subclass 300.

III. Claims 1-10, 25, and 33, drawn to peptide comprising SEQ ID NO: 11-16, classified in class 530, subclass 300.

IV. Claims 1, 3-5, 7, 9, 25, and 33, drawn to peptide comprising SEQ ID NO: 17, classified in class 530, subclass 300.

V. Claims 11-24, drawn to nucleic acid encoding peptide comprising SEQ ID NO: 1, 2, or 6-10, classified in class 536, subclass 23.1.

VI. Claims 11, 12, 14, 15, 17, 18, 20-22, and 24, drawn to nucleic acid encoding peptide comprising SEQ ID NO: 3-5, classified in class 536, subclass 23.1.

VII. Claims 11-24, drawn to nucleic acid encoding peptide comprising SEQ ID NO: 11-16, classified in class 536, subclass 23.1.

VIII. Claims 11, 12, 14, 15, 17, 18, 20-22, and 24, drawn to nucleic acid encoding peptide comprising SEQ ID NO: 17, classified in class 536, subclass 23.1.

IX. Claim 27, drawn to a method of treating cancer via peptide comprising SEQ ID NO: 1, 2, or 6-10, classified in class 514, subclass 2.

X. Claim 27, drawn to a method of treating cancer via peptide comprising SEQ ID NO: 3-5, classified in class 514, subclass 2.

XI. Claim 27, drawn to a method of treating cancer via peptide comprising SEQ ID NO: 11-16, classified in class 514, subclass 2.

XII. Claim 27, drawn to a method of treating cancer via peptide comprising SEQ ID NO: 17, classified in class 514, subclass 2.

XIII. Claims 26 and 28, drawn to a method of treating cancer via nucleic acid encoding peptide comprising SEQ ID NO: 1, 2, or 6-10, classified in class 514, subclass 44.

XIV. Claims 26 and 28, drawn to a method of treating cancer via nucleic acid encoding peptide comprising SEQ ID NO: 3-5, classified in class 514, subclass 44.

XV. Claims 26 and 28, drawn to a method of treating cancer via nucleic acid encoding peptide comprising SEQ ID NO: 11-16, classified in class 514, subclass 44.

XVI. Claims 26 and 28, drawn to a method of treating cancer via nucleic acid encoding peptide comprising SEQ ID NO: 17, classified in class 514, subclass 44.

XVII. Claims 29-32, drawn to a vaccine comprising peptide comprising SEQ ID NO: 1, 2, or 6-10, classified in class 514, subclass 2.

XVIII. Claims 29-32, drawn to a vaccine comprising peptide comprising SEQ ID NO: 3-5, classified in class 514, subclass 2.

XIX. Claims 29-32, drawn to a vaccine comprising peptide comprising SEQ ID NO: 11-16, classified in class 514, subclass 2.

XX. Claims 29-32, drawn to a vaccine comprising peptide comprising SEQ ID NO: 17, classified in class 514, subclass 2.

XXI. Claims 34-36, drawn to an antibody against a peptide comprising SEQ ID NO: 1, 2, or 6-10, classified in class 530, subclass 387.1.

XXII. Claims 34-36, drawn to an antibody against a peptide comprising SEQ ID NO: 3-5, classified in class 530, subclass 387.1.

XXIII. Claims 34-36, drawn to an antibody against a peptide comprising SEQ ID NO: 11-16, classified in class 530, subclass 387.1.

XXIV. Claims 34-36, drawn to an antibody against a peptide comprising SEQ ID NO: 17, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

The peptides of SEQ ID NO: 1-17 can be found aligned at page 5 of the specification. From this alignment, 4 patentably distinct groups of peptides have been determined. The first group (Group 1) of peptides are described in SEQ ID NO: 1, 2, and 6-10. These peptides differ from the second group (Group 2) comprising SEQ ID NO: 3-5 by non-conservative amino acid substitutions at Ile4Phe, Met10Asn/Asp, and Gln11Leu or Phe. The third group (Group 3) of peptides, SEQ ID NO: 11-16, are wholly different in amino acid composition from Groups I, and IV. Group IV, SEQ ID NO: 17, is not intuitively recognizable in any of Groups 1, 2, or 3. Thus, these Groups of peptides are considered to be patentably distinct one from the other because their sequences are not conserved or similar such that one skilled in the art would recognize their similarity or such that a search of one sequence would provide a search for all 17 amino acid sequences. Note that this is not an election of species; rather, the election of Group 1, for example, will be an election of SEQ ID NO: 1, 2, and 6-10 and only those sequences will be searched.

If Applicants believe that their sequences are so overlapping as to be obvious variants of each other, Applicants may choose a single sequence for search, this sequence being a representative sequence of all sequences or a designated subset of the sequences, as Applicant may choose. If Applicant present a single sequence to represent all sequences or a subset of sequences claimed, it will be understood that if this sequence or any sequence is found, the remaining sequences will be considered to be obvious variants of the found sequence.

Accordingly, for the same reasons, the polynucleotides, antibodies, vaccines, and methods are divided into separate inventions based on these groups of peptides.

The nucleic acids of Inventions V-VIII are related to the peptides of Inventions I-IV, respectively, by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention I-IV are related to the antibodies of Invention XXI-XXIV, respectively, and the vaccines of Inventions XVII-XX, respectively, by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Invention V-VIII and the antibody of Invention XXI-XXIV, respectively, and the vaccines of Inventions XVII-XX, respectively, are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody or vaccine. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

The products of Inventions I-VIII and XVII-XXIV differ in structure and in function. Therefore, Inventions I-VIII and XVII-XXIV are patentably distinct one from the other.

Inventions I-IV and Inventions IX-XII, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ∋ 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as to make vaccines or antibodies.

Inventions V-VIII and Inventions XIII-XVI, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ∋ 806.05(h)). In the instant case the product as claimed can be used in a materially different process such in the recombinant production of protein.

Inventions XXI-XXIV and Inventions XVII-XX, respectively, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ∋ 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as to purify proteins.

The product of Inventions I-IV and XVII-XXIV are not used in the method of Inventions XIII-XVI. Therefore, Inventions I-IV and XVII-XXIV are patentably distinct from Invention Inventions XIII-XVI.

The product of Inventions V-VIII and XVII-XXIV are not used in the method of Inventions IX-XII. Therefore, Inventions V-VIII and XVII-XXIV are patentably distinct from Invention Inventions IX-XII

The methods of Inventions IX-XVI require different products and steps and have different endpoints. Therefore, Inventions IX-XVI are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

> The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson PhD

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

There is thus provided, according to one embodiment of the invention, a peptide comprising at least one epitope recognized by a BAT monoclonal antibody, selected from:

(SEQ ID NO 1) Pro Arg Arg Ile Lys Pro Arg Lys Ile Met Leu Gln

(SEQ ID NO 2) Pro Arg Arg Ile Lys Pro Arg Lys Ile Met Leu Gln-amide

(SEQ ID NO 3) Pro Arg Arg Phe Lys Pro Arg Lys Ile Asn/Asp Leu Gln

(SEQ ID NO 4) Pro Arg Arg Ile Lys Pro Arg Lys Ile Asn/Asp Phe Gln

(SEQ ID NO 5) Pro Arg Arg Ile Lys Pro Arg Lys Ile Asn/Asp Leu Gln

(SEQ ID NO 6) Pro Arg Arg Ile Lys Ala Arg Lys Ile Met Leu Gln

(SEQ ID NO 7) Pro Arg Lys Ile Lys Pro Arg Lys Ile Met Leu Gln

(SEQ ID NO 8) - - Arg Ile Lys Pro Arg Lys Ile Met Leu Gln

(SEQ ID NO 9) Pro Arg Arg Ile Lys Pro Arg Lys Ile Met - -

(SEQ ID NO 10) acetyl-Pro Arg Arg Ile Lys Pro Arg Lys Ile Met Leu Gln

(SEQ ID NO 11) Gln Arg Ile Leu Gln Gln Ile Asn Leu Pro Arg Ile

(SEQ ID NO 12) Gln Arg Ile Leu Gln Gln Ile Asn Leu Ala Arg Ile

(SEQ ID NO 13) Gln Arg Ile Leu Gln Glu Ile Asn Leu Pro Arg Ile

(SEQ ID NO 14) Gln Arg Ile Leu Gln Gln Ile Asn Leu Pro Lys Ile

(SEQ ID NO 15) - - Ile Leu Gln Gln Ile Asn Leu Pro Arg Ile

(SEQ ID NO 16) Gln Arg Ile Leu Gln Gln Ile Asn Leu Pro - -

(SEQ ID NO 17) Asn Arg Ile Arg Thr Asn Thr Lys Leu Met Asn Ser

According to certain currently preferred embodiments, the present invention provides a peptide comprising at least one epitope recognized by a BAT monoclonal antibody selected from SEQ ID NOs 1, 6, 8, 9, 10, 14 and 16.

According to another particular embodiment, the present invention provides a peptide comprising at least one epitope recognized by a BAT monoclonal antibody, selected from: a peptide, a fragment of a peptide, a homolog, a variant, a derivative or a salt of a peptide having the sequence of any one of SEQ ID NOs 1 through 17, wherein the biological activity of said peptides or fragments is retained.

According to yet another particular embodiment, the present invention provides a combination of any one of the peptides comprising at least one epitope recognized by a BAT monoclonal antibody, selected from: a peptide, a fragment of a peptide, a homolog, a variant, a derivative or a salt of a peptide having the sequence of any one of SEQ ID NOs 1 through 17, wherein the biological activity of said peptides or fragments is retained.